

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

**EP 0 901 391 B1**

(12)

**EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention  
of the grant of the patent:  
**22.01.2003 Bulletin 2003/04**

(51) Int Cl.7: **A61M 5/24, A61M 5/32**

(21) Application number: **97920839.4**

(86) International application number:  
**PCT/GB97/01232**

(22) Date of filing: **06.05.1997**

(87) International publication number:  
**WO 97/041908 (13.11.1997 Gazette 1997/49)**

(54) **SAFETY SYRINGE**

**SICHERHEITSSPRITZE**

**SERINGUE DE SECURITE**

(84) Designated Contracting States:  
**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC  
NL PT SE**  
Designated Extension States:  
**AL LT LV RO SI**

(72) Inventors:  
• **VAN DER MEYDEN, Hendrikus, Johannes**  
**Midrand, Gauteng 1685 (ZA)**  
• **WADMAN, Alexis, Adrian, Filipe**  
**Bedfordview, Gauteng 2008 (ZA)**

(30) Priority: **03.05.1996 ZA 9603499**

(74) Representative: **Fenlon, Christine Lesley**  
**Haseltine Lake & Co.,**  
**Imperial House,**  
**15-19 Kingsway**  
**London WC2B 6UD (GB)**

(43) Date of publication of application:  
**17.03.1999 Bulletin 1999/11**

(73) Proprietor: **Nordway Limited**  
**Douglas, Isle of Man IM99 1QF (GB)**

(56) References cited:  
**EP-A- 0 581 523** **DE-A- 4 120 267**  
**GB-A- 728 248** **US-A- 5 320 606**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

**EP 0 901 391 B1**

## Description

### FIELD OF THE INVENTION

[0001] This invention relates to a safety syringe:

[0002] The specification of EP 581 523A discloses a syringe comprising a barrel with a reciprocable piston having a liquid passage between the piston ends. The outer piston end is connectable to a needle, and an open ended tubular sheath having a needle end and a handle end, and being slidable over the barrel, is attachable to the piston, to extend around the barrel when the piston is toward the handle end of the barrel. The piston is selectively detachable from the sheath, and is movable, after such detachment and with retraction of the barrel from the sheath, to selectively draw a needle means attached to the piston into the sheath.

[0003] U S Patent specification No 5,320,606 discloses a disposable medical syringe which has a hollow plunger to receive a used inoculation needle. The syringe has a hollow syringe barrel, open on one end and dosed on the other. A hollow plunger assembly, which extends out the open end of the syringe barrel, has a hollow tube with a fixed seal attached at one end. At the other end of the plunger assembly, a needle holder is sized to slide within the hollow tube. The sliding seal and needle holder are biased toward each other by a stretched, resilient tube that has a fluid passageway passing through the sliding seal, resilient tube, and needle holder. The needle holder is normally locked at one end of the plunger assembly by a locking means. As the syringe is collapsed, the syringe barrel trips the locking means to permit the needle holder, and attached inoculation needle, to be retracted into the hollow tube. The three components - inoculation needle, hollow tube, and syringe barrel - are telescoped together by this action to compact the throw-away unit with the used inoculation needle resting in a position protected by the double outer walls.

### BACKGROUND TO THE INVENTION

[0004] With the increasing risk of infection through needle injuries, there is a demand for a syringe which can be used and disposed of in a manner which reduces the risk of such injury.

### OBJECT OF THE INVENTION

[0005] It is an object of this invention to provide a safety syringe.

### SUMMARY OF THE INVENTION

[0006] In accordance with this invention there is provided a syringe comprising:

a generally tubular protective sheath carrying piston

engaging formations and having a needle end and an opposite rear end; a piston including an elongate piston body and a piston head, there being a fluid pathway through the head and longitudinally through the body, the piston body being operatively locatable to extend within the sheath and be engaged by the piston engaging formations, with the piston head outside the sheath and connected to and in fluid communication with the piston body; a barrel which is slidable in a discharge stroke in use over the outside of the operatively located piston head and along the sheath to a discharged position, to thereby release the piston engaging formations, and grip the released piston, the barrel being oppositely slidable from the discharged position to withdraw the released piston substantially from the sheath to a safe locked position relative to the sheath; characterised in that the barrel is shaped and dimensioned to be slidable over the outside of the protective sheath and the said piston engaging formations comprise clips and stops carried by the piston body and sheath to operatively lock the piston body relative to the sheath to hold a needle used with the syringe inside the sheath before and after use.

[0007] Preferably in a first embodiment of the invention the piston body has a front and a rear end, with front clips and rear clips thereon, and the sheath has stops at its rear end, the clips and stops being arranged to enable the piston body to be inserted into the sheath with the rear clips of the piston body engaging the stops of the sheath and locking the piston body against withdrawal from and insertion into the sheath, in that rotational orientation with the sheath, and being further arranged to enable movement of the barrel to its discharged position to release the rear clips of the piston body, and to enable the front clips of the piston body to engage the stops on movement of the piston body to the safe locked position.

[0008] There is provided for the sheath to have a first and second axial keyway means, the first keyway means having a cross sectional shape designed to guide a clip rotating therein in use into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational movement of a clip therein in use.

[0009] Further, each of the first and second keyway means are a pair of diametrically opposed matching keyways, with the pairs located at 90 degrees to each other in cross-sectional orientation of the sheath.

[0010] One of the said stops is a transverse clip stop provided in each keyway of a pair, the clip stop of the first keyway pair being located further into the sheath interior than the clip stop of the second keyway pair.

[0011] Preferably, the front clips of the piston body form keyway slides, and have opposed clipping formations, comprising a front formation which is able to slide

over the stops in a forward direction only, and a rear formation which is able to slide over the stops in a withdrawal direction only.

[0012] The rear clips of the piston body may have opposed clipping formations, comprising a forward clipping formation slidable over the stops on insertion into the sheath, and a rear formation which abuts the stops when the piston body is slid into the sheath.

[0013] Preferably, the rear formation of the rear clips of the piston body is shaped to co-operate with the piston head, on movement of the piston head with the barrel at the end of a discharge stroke in use, to disengage the forward formation of the rear clip from its stop in use.

[0014] Alternatively, the sheath carries stops comprising barbed flaps arranged to engage slots on the piston.

[0015] Preferably, these flaps are part of the sheath wall and project axially rearwardly from a hinged portion of the sheath at the needle end of the sheath, the sheath having free ends engagable by the end of the barrel at the end of a discharge stroke to hinge the flaps outwardly and out of engagement with the slots.

[0016] Further, the slots are carried in diametrically opposed piston clips which extend axially from the piston body at a front end thereof, and are resiliently inwardly deformable.

[0017] The sheath may have the same keyway configuration. To this end the sheath may have a first and second axial keyway means, the first keyway means having a cross sectional shape designed to guide a clip rotating therein in use into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational movement of a clip therein in use, each keyway means having a transverse stop at the rear end of the sheath, and in which the clips form keyway slides, arranged to enable insertion of the piston body into the first keyway means with the clip slots engaged in the first keyway means stop, and to enable rotation of the piston body in this location to guide the clips into the second keyway means, free of the second keyway means stop in an insertion direction of the piston body into the sheath, and further to enable the withdrawal of the piston body with the clips in the second keyway means to a position where the clip slots engage the stop at the second keyway means to lock the piston body against insertion and withdrawal.

[0018] There is also provided for the piston head to be integral with the piston body.

[0019] A further feature of the invention provides for the piston to be separate from the piston body and to be connectable to the piston body to form the piston.

[0020] In one embodiment the protective sheath and piston body are operatively locatable relative to each other prior to use into a packaged condition in which the end of the elongate piston body remote from the piston head end is engaged in the piston engaging formation, the fluid pathway being formed by a hypodermic needle running lengthways through the piston body with its front end extending out of the piston body and contained with-

in and protected by the sheath, and with its rear end contained within and protected by the piston body.

## **BRIEF DESCRIPTION OF THE DRAWINGS**

[0021] Embodiments of the invention are described below by way of example only, and with reference to the accompanying drawings, in which:

- |    |           |  |
|----|-----------|--|
| 5  | Figure 1  | is a sectioned longitudinal side view of a barrel and piston head according to the invention;  |
| 10 | Figure 2  | is a sectioned longitudinal side view of a piston body and a sheath according to the invention;  |
| 15 | Figure 3  | is a sectioned longitudinal side view as for Figure 2, but rotated through 90 degrees around the sheath and piston body axis;  |
| 20 | Figure 4  | is a partially cut away isometric view of the piston head connected to the piston body, and inserted in the sheath;  |
| 25 | Figure 5  | is an isometric view of the rear end of the piston body;   |
| 30 | Figure 6  | is an isometric view of the front end of the piston body;  |
| 35 | Figure 7  | is an isometric view of the rear entrance to the sheath;   |
| 40 | Figure 8  | is an isometric view of the rear end of the sheath cut away for explanatory purposes;  |
| 45 | Figure 9  | is a view of the front of the piston body inserted in the sheath in a packaged position;   |
| 50 | Figure 10 | is a sectioned longitudinal side view of the piston body and sheath after a relative one quarter turn of the piston body within the sheath from the packaged position; |
| 55 | Figure 11 | is an isometric view of the configuration of the embodiment in Figure 10;  |
|    | Figure 12 | is a side view of the piston body fully inserted within the sheath in an armed position.   |
|    | Figure 13 | is a partly sectioned isometric view of the rear of the piston body in the position of Figure 12;  |

- Figure 14** is a view of the assembled syringe with barrel and piston head connected to the sheath and piston body in a loaded condition;
- Figure 15** is a side view of the syringe shown in Figure 14 after a discharge stroke;
- Figure 16** is a longitudinal side view of the syringe with the barrel in a fully depressed unlocked position;
- Figure 17** is a longitudinal side view of the barrel of the syringe with the barrel withdrawn to a safe position;
- Figure 18** is a part sectioned isometric view of the front of the piston body clipped into the rear of the sheath with the syringe in the safe position, as shown in Figure 17;
- Figure 19** is a longitudinal side view and cross-section of a barrel of an alternative embodiment of the invention;
- Figure 20** is a longitudinal cross-section of a piston body and integral piston head of the alternative embodiment;
- Figure 21** is a sectioned longitudinal view of a sheath of the alternative embodiment;
- Figure 22** is a party sectioned isometric view of the inter-action between the front end of a piston body, the sheath and a piston barrel in the alternative embodiment;
- Figure 23** is an isometric view of the configuration of Figure 22 showing the releasing action of the flaps.

#### **DETAILED DESCRIPTION OF THE DRAWINGS WITH REFERENCE TO THE DRAWINGS**

**[0022]** Referring to Figures 1 to 3, a drug delivery system is in the form of a syringe having a barrel (1), a piston with an elongate piston body (2), and a piston head (3), and a sheath (4).

**[0023]** The barrel is tubular with a dosed rear end (5) and an open front or needle end (6), and is preferably made of glass. A stopper may alternatively be provided to dose the rear end, enabling the use of a simple length of glass tube for the barrel.

**[0024]** Referring to Figures 1 and 4, the piston head (3) is of elastomeric material and is reciprocable within the barrel. It has integral front and rear sealing rings (7) and (8) therearound at each axial end, and a blind axial passageway (9) extending into a rear axial end (10)

within a conical projection (11). The projection extends past the front sealing ring (7) where the projection end (12) forms an integral plug to the blind end of the passageway.

**[0025]** The front sealing ring carries an annular radially inwardly extending lip (13) so that opposed recesses (13a) are provided to allow a twist-clip action when the piston is operatively located.

**[0026]** The piston body (2) (Figures 2, 3 and 10) has a central hypodermic needle (14) running in its length. The needle (14) extends from a front or needle end (15) to end (16) located just short of, and within, an opposite rear end (17) of the piston body (2).

**[0027]** The rear end (17) of the piston body is shown in more detail in Figures 4 and 5. It is tubular, open at the rear, and surrounds the needle rear end (16) (not shown in Figs. 4 and 5) as it extends into the interior of the tubular space (18).

**[0028]** On diametrically opposed sides of the tubular rear end are hinged rear piston body clips (20) and (21) (not shown in Figs. 4 and 5). The clips lie within the tubular wall, and extend axially from hinges at their rear ends, to be resiliently pivotable into and out of the tubular space (18). Each clip has two spaced apart outwardly projecting ramp catches, with one catch (23) at its free end and one ramp (24) at its hinged end. The slopes (25) of the ramp catches face away from each other, and the ledges (26) oppose each other.

**[0029]** Positioned at 90 degrees to the clips (20) and (21), on the outside of the rear end of the piston body, are diametrically opposed lateral stops (30).

**[0030]** On the outside of the rear edge are diametrically opposed lugs (27) arranged to co-operate with recesses (13a) of the piston head.

**[0031]** The front end of the piston body is shown in more detail in Figure 6. Diametrically opposed pairs of barbed dipping formations (32) extend outwardly from the piston body. Each pair (32) has one front piston body clip (33) extending from the body acutely and axially towards the rear of the piston body, and another front piston body clip (34) similarly extending towards the front of the body in the same plane as its mate, in the form of opposed barbs. The ends of the clips of a pair stop short of each other with a gap (35) between them.

**[0032]** Referring to Figures 2, 3, 7 and 8, the sheath (4) is shown. It has a rear end (38) and a front or needle end (39). The entrance to the rear end, (Figures 7 and 8) is divided into four quarters by two pairs of matching axial keyways. Each keyway of one pair (40) is bound at its axial sides by edges which extend inwardly and towards each other in the manner of a dovetail slot. These keyways have transverse stops (41) which run from edge (42) to edge (42) at the height of the edges, just inwardly of the rear end. Apart from these stops, the keyways run the length of the sheath uninterrupted, and are referred to as the "long" keyways.

**[0033]** The other pair of keyways (44), have no abrupt edges. Each keyway extends smoothly in cross-section,

from and at the height of, the axial edges (42) to a central depth equal to the depth of the long keyways. The second keyways each have a transverse stop (45) extending arcuately across them at the height of the edges (42). The stops (45) are spaced inwardly of the stops (41) from the rear end of the piston body. The smooth cross-sectional shape of the second pair of keyways provide a cam action in use, and these keyways are referred to as the "cam" keyways.

**[0034]** The sheath has two finger grips (48) set diametrically opposite each other, and extending from the front end (39) of the sheath outwardly.

**[0035]** In use, the syringe is provided in a packaged condition as illustrated in Figures 1 to 3. This position is achieved by preloading the barrel (1) with a required fluid, and inserting the piston head (3) therein to act as a stopper. Suitable covering or other sealing may be provided for the purposes of maintaining sterility. The piston body (2) is inserted into the sheath at the entrance end thereof. This is done by aligning the piston body to slide the pair of clips (32) down the can keyways causing the clips (33) to clip over the stop (45) and the dips (34) to lock behind them. The piston body in this rotational orientation, is locked in position. The needle is fully contained within the sheath and is protected.

**[0036]** To use the syringe, the piston body is rotated one quarter turn (Figure 10) which causes the both sets of dips (33) and (34) to be radially depressed by the shape of the camming surface of the cam keyways. As the dips align with the long keyways at the end of the quarter turn, they clip resiliently outwardly into them.

**[0037]** The stops in the keyways are arranged to cause the clip (34) to clip outwardly in the keyway past the stop of the long keyway. This position is shown in Figure 11 in more detail.

**[0038]** The piston body may now be slid freely into the sheath with the needle protruding from the front sheath end. As shown in Figure 12, the piston body is slid until the front catch (23) of the dips (20) at the rear piston body end clip over the transverse stops of the cam keyway (45).

**[0039]** The piston is oriented so that the rear dips (20) are at 90 degrees to the front barbed dipping formations (32). In this position, the lateral stops (30) of the rear piston end abut the stops (41) of the long keyway, with the rear ramp catch (24) outside the sheath. The piston body is now locked within the sheath against both further insertion, and withdrawal.

**[0040]** The barrel and piston head, forming a pre-packaged dosage of particular fluid, is now inserted over the piston and the sheath. This causes the rear needle end (16) to pierce the end (12) of the projection, and enter the passageway (9), thus causing a complete passageway from the rear end of the piston head, through the needle and the piston body, to the free end of the needle projecting from the sheath. It will be appreciated that at least a piston head portion that reciprocates within the barrel should remain outside the sheath, to avoid

the necessity of intermediate seals, and a gripping mechanism to extract the piston. This position is shown in Figure 14.

**[0041]** Further depression of the barrel over the piston, with the finger supported on the finger grips (48), causes a discharge of the fluid in the piston through the piston head and out of the needle. At the fully depressed position the rear end of the barrel abuts the piston head. (Figure 15).

**[0042]** To unlock the piston head and piston body, the barrel is further depressed to cause the front flanges of the piston head (3) to slide further over the rear end of the piston body (2). This is shown in Figure 16, and in detail in Figure 4. With the piston head contained within the barrel, it cannot expand outwardly away from the dips (20) and the piston head lip (13) rides over the slope (25) of ramp (24), thus forcing it to hinge inwardly, and displace the catch (23) from its engaged position over the stop (45).

**[0043]** The barrel is now withdrawn from the sheath, taking the piston head and piston with it under force of friction. The barbed dips (33) and (34) slide in the long keyway until they engage at the top in the entrance to the rear end of the sheath.

**[0044]** As shown in Figure 18, the rear barbed clips (34) clip over the stops (41) of the long keyway, and the barbed clips (33) and (34) engage against the stops (41). The piston body is now locked in position in the long keyways, with the stops (41) engaged in the gap (35) between the dips. It cannot be further withdrawn, nor inserted, and any rotation is arrested by the dovetail edges (42) of the long keyway.

**[0045]** The barrel may be further slid right off the piston body if desired, but the needle is drawn up inside the sheath to be fully contained therein, and safe from any accidental contact

**[0046]** Referring to Figures 19 to 23 an alternative embodiment is shown. A barrel (51) is substantially similar to the barrel of the first embodiment, of Figures 1 to 18, save that it has a central rod (52) extending down from a rear end (53) past a front end (54) of the barrel. The front edges (55) of the barrel are chamfered downwardly towards the barrel centre.

**[0047]** A piston (60) (Figure 20) has an integral piston head (61), reciprocable within the barrel, and an elongate body (62) terminating in a needle fitting (63) for receiving a conventional hypodermic needle. Diametrically opposed set of dips (64) are provided at the front end adjacent the needle fitting (63). An axial passageway (65) passes: through the piston from the head to the needle end. The passageway is shaped to receive the barrel rod when the barrel is slid over the piston from the head end

**[0048]** A sheath (70) has a rear end (71) and the same configuration (72) of keyways as described with reference to the first embodiment, i.e. a pair of long keyways having transverse stops and a pair of cam keyways having transverse stops. The sheath is tubular having finger

grips (73), and differs from the first embodiment in that it has front stops (74) in the form of barbed flaps, located diametrically opposed to each other.

[0049] This embodiment functions substantially similarly to the first embodiment, save that with the integral piston head (61), the clips (64) on the piston body and stops (74) on the sheath are used to unlock the piston.

[0050] The piston body clips (64) are resiliently inwardly movable, and each has a slot therein comprising a centrally located recess (66). The stops (74), comprising barbed flaps, are part of the wall of the sheath, and are hinged at a front end (75) with a protruding ramp catch (76). The slope of the ramp faces rearwardly, so that with the piston in the barrel, the clip (64) can move down the sheath in an arming motion and engage the stop (74) in the recess (66).

[0051] The barrel can now be withdrawn leaving the piston behind, secured by the stops, i.e. flaps, (74). This enables fluid to be drawn into the barrel through the needle. The stops (74) are released from under the barrel, and under the biasing of the clips (64), the stops (74) protrude slightly outwardly above the sheath surface. The fluid is discharged by depressing the barrel over the piston. On this discharge stroke the chamfered front end of the barrel contacts the protruding sheath steps (74) and lifts them outwardly out of engagement with the piston clips (64). This position is shown in detail in Figure 23.

[0052] The piston is now held within the barrel under friction force, and can be withdrawn with the barrel to a safe position within the sheath. The recesses (66) of the clips (64) engage with the transverse stops of the long keyway, locking the piston.

[0053] In use, the syringe is assembled by inserting the piston (60), located fully within the barrel, into the sheath (70). This is done by inserting the clips (64) in the cam keyway, rotating them to align them in the long keyways, and sliding the piston fully into the sheath. The clips (64) bend inwardly to engage with the stops (74), since the barrel rides over the stops (74) and holds them against outward hinging. This is shown in more detail with reference to Figure 22.

## Claims

### 1. A syringe comprising:

a generally tubular protective sheath (4; 70) carrying piston engaging formations (41, 45; 74) and having a needle end (39) and an opposite rear end (38; 71);

a piston (2, 3; 60) including an elongate piston body (2; 62) and a piston head (3; 61), there being a fluid pathway (14; 65) through the head (3; 61) and longitudinally through the body (2; 62), the piston body (2; 62) being operatively locatable to extend within the sheath (4; 70) and

be engaged by the piston engaging formations (41, 45; 74), with the piston head (3; 61) outside the sheath (4; 70) and connected to and in fluid communication with the piston body (2; 62);

a barrel (1; 51) which is slidable in a discharge stroke in use over the outside of the operatively located piston head (3; 61) and along the sheath (4; 70) to a discharged position, to thereby release the piston engaging formations (41, 45; 74), and grip the released piston (2, 3; 60), the barrel (1; 51) being oppositely slidable from the discharged position to withdraw the released piston (2, 3; 60) substantially from the sheath (4; 70) to a safe locked position relative to the sheath (4; 70); characterised in that the barrel (1; 51) is shaped and dimensioned to be slidable over the outside of the protective sheath (4; 70) and the said piston engaging formations (41, 45; 74) comprise clips (33, 34 and 20, 21; 64) and stops (41, 45; 74) carried by the piston body (2; 62) and sheath (4; 70) to operatively lock the piston body (2; 62) relative to the sheath (4; 70) to hold a needle used with the syringe inside the sheath (4; 70) before and after use.

2. A syringe as claimed in claim 1, in which the piston body (2) has a front and a rear end, and front clips (33, 34) and rear clips (20, 21) thereon, and the sheath (4) has stops (41, 45) at its rear end (38), the clips (20, 21, 33, 34) and stops (41, 45) being arranged to enable the piston body (2) to be inserted into the sheath (4) with the rear clips (20, 21) of the piston body (2) engaging the stops (41, 45) of the sheath and locking the piston body (2) against withdrawal from and insertion into the sheath (4), in that rotational orientation with the sheath (4), and being further arranged to enable movement of the barrel (1) to its discharged position to release the rear clips (20, 21) of the piston body and to enable the front clips (33, 34) of the piston body to engage the stops (41, 45) on movement of the piston body (2) to the safe locked position.

3. A syringe as claimed in claim 2, in which the sheath (4) has first and second axial keyway means (44, 40), the first keyway means (44) having a cross-sectional shape designed to guide a clip rotating therein in use into the second keyway means (40), and the second keyway means (40) having abrupt edges designed to prevent rotational movement of a clip therein in use.

4. A syringe as claimed in claim 3, in which the first and second keyway means are formed by respective pairs of diametrically opposed matching keyways (44, 40), with the pairs located at 90 degrees to each other in cross-sectional orientation of the

sheath (4).

5. A syringe as claimed in claim 4, in which one of the said stops (41, 45) is a transverse clip stop (45) provided in each keyway of a pair, the clip stop (45) of the first keyway pair being located further into the sheath interior than the clip stop (41) of the second keyway pair. 5
6. A syringe as claimed in claim 5, in which the front clips (33, 34) of the piston body (2) form keyway slides, and have opposed clipping formations, comprising a front formation which is able to slide over the stops in a forward direction only, and a rear formation which is able to slide over the stops in a withdrawal direction only. 10 15
7. A syringe as claimed in claim 6, in which the rear clips (20, 21) of the piston body (2) have opposed clipping formations, comprising a forward clipping formation slidable over the stops (45) on insertion into the sheath, and a rear formation which abuts the stops when the piston body (2) is slid into the sheath (4). 20 25
8. A syringe as claimed in claim 7, in which the rear formation of the rear clips (20, 21) of the piston body is shaped to co-operate with the piston head (3), on movement of the piston head (3) with the barrel (1) at the end of a discharge stroke in use, to disengage the forward formation of the rear clip from its stop in use. 30
9. A syringe as claimed in claim 1, in which the stops (74) on the sheath (70) comprise barbed flaps arranged to engage slots (66) on the piston (60). 35
10. A syringe as claimed in claim 9, in which the flaps are part of the sheath wall and project axially rearwardly from a hinged portion of the sheath (70) at the needle end of the sheath (70), the sheath (70) having free ends (75) engagable by the end (54) of the barrel (51) at the end of a discharge stroke to hinge the flaps outwardly and out of engagement with the slots (66). 40 45
11. A syringe as claimed in claim 10, in which the slots (66) are carried in diametrically opposed piston clips (64) which extend axially from the piston body (62) at a front end thereof, and are resiliently inwardly deformable. 50
12. A syringe as claimed in claim 11, in which the sheath (70) has first and second axial keyway means, the first keyway means having a cross-sectional shape designed to guide a clip rotating therein into the second keyway means, and the second keyway means having abrupt edges designed to prevent rotational 55

movement of a clip therein in use, each keyway means having a transverse stop at the rear end of the sheath (70), and in which the clips (64) form keyway slides, arranged to enable insertion of the piston body (62) into the first keyway means with the clip slots (66) engaged in the first keyway means stop, and to enable rotation of the piston body (62) in this location to guide the clips (64) into the second keyway means, free of the second keyway means stop in an insertion direction of the piston body into the sheath (70), and further to enable the withdrawal of the piston body (62) with the clips (64) in the second keyway means to a position where the clip slots (66) engage the stop at the second keyway means to lock the piston body (62) against insertion and withdrawal.

13. A syringe as claimed in any one of the preceding claims, in which the piston head (3) is integral with the piston body (2).
14. A syringe as claimed in any one of claims 1 to 12, in which the piston head (3) is separate from the piston body (2) and is connectable to the piston body (2) to form the piston.
15. A syringe according to any one of the preceding claims, the protective sheath (4) and piston body (2) being operatively locatable relative to each other prior to use into a packaged condition in which the end of the elongate piston body (2) remote from the piston head end is engaged in the piston engaging formation (41, 45), the fluid pathway being formed by a hypodermic needle (14) running lengthways through the piston body (2) with its front end (15) extending out of the piston body (2) and contained within and protected by the sheath (4), and with its rear end (15) contained within and protected by the piston body (2).

#### Patentansprüche

##### 1. Spritze, umfassend

eine in der Regel rohrförmige Schutzhülle (4; 70) mit Kolbeneingriffsstrukturen (41, 45; 74), einem Nadelende (39) und einem entgegengesetzten rückseitigen Ende (38; 71); einen Kolben (2, 3; 60) mit einem länglichen Kolbenkörper (2; 62) und einem Kolbenkopf (3; 61), wobei: Fluidwege (14; 65) da durch den Kopf (3; 61) und längs durch den Körper (2; 62) sind; der Kolbenkörper (2; 62) funktionell so einrichtbar ist, dass er sich innerhalb der Hülle (4; 70) erstreckt und in Eingriff ist mit den Kolbeneingriffsstrukturen (41, 45; 74); der Kolbenkopf (3, 61) außerhalb der Hülle (4; 70) ist und



in Fluidverbindung mit dem Kolbenkörper (2; 62);

eine Trommel (1; 51), die bei Gebrauch in einem Ausstoßschub über die Außenseite des funktionell angeordneten Kolbenkopfs (3; 61) und längs der Hülle (4; 70) in die Ausstoßstellung verschieblich ist, wobei die Kolbeneingriffsstrukturen (41, 45; 74) frei werden und in den freien Kolben (2, 3; 60) eingreifen und die Trommel (1; 51) aus der Entladestellung wegverschieblich ist, so dass der freie Kolben (2, 3; 60) im Wesentlichen aus der Hülle (4; 70) zurück in eine sichere Sperrstellung zur Hülle (4; 70) gezogen werden kann;

**dadurch gekennzeichnet, dass**

die Trommel (1; 51) so geformt und bemessen ist, dass sie über die Außenseite der Schutz-

hülle (4; 70) verschieblich ist, die Kolbeneingriffsstrukturen (41, 45; 74) Klemmen (33, 34 und 20, 21; 64) und Anschläge (41, 45; 74) aufweisen, die auf dem Kolbenkörper (2; 62) und der Hülle (4; 70) sind, welche funktionell den Kolbenkörper (2; 62) bezüglich der Hülle (4; 70) sichern, so dass die mit der Spritze verwendete Nadel vor und nach Gebrauch in der Hülle (4; 70) gehalten wird.

2. Spritze nach Anspruch 1, wobei der Kolbenkörper (2) ein stirn- und ein rückseitiges Ende besitzt, stirnseitige (33, 34) und rückseitige Klemmen (20, 21) darauf und die Hülle (4) Anschläge (41, 45) am rückseitigen Ende (38) besitzt, wobei die Klemmen (20, 21, 33, 34) und die Anschläge (41, 45) so angeordnet sind, dass der Kolbenkörper (2) in die Hülle (4) eingeführt werden kann, die rückseitigen Klemmen (20, 21) des Kolbenkörpers (2) mit den Anschlägen (41, 45) der Hülle eingreifen und den Kolbenkörper (2) gegen ein Zurückziehen bzw. ein Hineinschieben in die Hülle (4) sichern bei dieser Drehausrichtung mit der Hülle (4), und dass sie zudem so angeordnet sind, dass sie eine Bewegung der Trommel (1) in die Ausstoßstellung erlauben, wobei bei einer Bewegung des Kolbenkörpers (2) in die sichere Sperrstellung die rückseitigen Klemmen (20, 21) des Kolbenkörpers freigegeben werden und die stirnseitigen Klemmen (33, 34) des Kolbenkörpers mit den Anschlägen (41, 45) in Eingriff gelangen.
3. Spritze nach Anspruch 2, wobei die Hülle (4) erste und zweite axiale Schließweeinrichtungen (44, 40) aufweist, die ersten Schließweeinrichtungen (44) eine solche Querschnittsgestalt hat, dass bei Gebrauch eine Klemme darin drehend in die zweite Schließweeinrichtung (40) geführt wird und die zweite Schließweeinrichtung (40) solch abrupte

Kanten besitzt, dass bei Gebrauch eine Drehbewegung der Klemme darin verhindert ist.

4. Spritze nach Anspruch 3, wobei die erste und die zweite Schließweeinrichtung von entsprechenden Paaren diametral entgegengesetzt liegender passender Schließwege (44, 40) gebildet werden, wobei die Paare zueinander 90° in Querschnittsausrichtung der Hülle (4) haben.
5. Spritze nach Anspruch 4, wobei in jedem Schließweg eines Paares einer der Anschläge (41, 45) ein Querklemmenanschlag (45) ist und der Klemmenanschlag (45) des ersten Schließwegpaars weiter innen in der Hülle ist als der Klemmenanschlag (41) des zweiten Schließwegpaars.
6. Spritze nach Anspruch 5, wobei die stirnseitigen Klemmen (33, 34) des Kolbenkörpers (2) Schließweggleitflächen bilden und gegenüberliegende Klemmenausbildungen besitzen, umfassend eine stirnseitige Ausbildung, die nur in Vorwärtsrichtung über die Anschläge gleiten kann sowie eine rückseitige Ausbildung, die nur bei einem Zurückziehen über die Anschläge gleiten kann.
7. Spritze nach Anspruch 6, wobei die rückseitigen Klemmen (20, 21) des Kolbenkörpers (2) entgegengesetzte Klemmenausbildungen besitzen, umfassend eine Vorwärts-Klemmenausbildung, die über die Anschläge (45) bei einem Einschieben in die Hülle gleiten kann, sowie rückseitige Ausbildungen, welche die Anschläge beanschlagen, ist der Kolbenkörper (2) in die Hülle (4) eingeschoben.
8. Spritze nach Anspruch 7, wobei die rückseitigen Ausbildungen der rückseitigen Klemmen (20, 21) des Kolbenkörpers so geformt sind, dass sie bei Gebrauch mit dem Kolbenkopf (3) bei einer Bewegung des Kolbenkopfs (3) mit der Trommel (1) am Ende eines Ausstoßschubs kooperieren, so dass bei Gebrauch die Vorwärtsausbildung der rückseitigen Klemme aus ihrem Anschlag gelöst wird.
9. Spritze nach Anspruch 1, wobei die Anschläge (74) auf der Hülle (70) mit Widerhaken versehene Klappen aufweisen, die zu einem Eingriff mit den Schlitten (66) auf dem Kolben (60) angeordnet sind.
10. Spritze nach Anspruch 9, wobei die Klappen Teil der Hüllenwand sind und axial rückseitig aus einem angelenkten Teil der Hülle (70) am Nadelende der Hülle (70) vorstehen und die Hülle (70) am Ende eines Auslassschubs freie Enden (75) für einen Eingriff mit dem Ende (54) der Trommel (51) besitzt, so dass die Klappen nach außen und aus dem Eingriff mit den Schlitten (66) verschwenken.

11. Spritze nach Anspruch 10, wobei die Schlitze (66) in diametral gegenüberliegenden Kolbenklemmen (64) sind, welche axial aus dem Kolbenkörper (62) an dessen Stirnende vorstehen und welche elastisch nach innen verformbar sind.

5

12. Spritze nach Anspruch 11, wobei

die Hülle (70) erste und zweite axiale Schließweeinrichtungen besitzt,  
 die erste Schließweeinrichtung eine so gestaltete Querschnittsform besitzt, dass eine sich darin drehende Klemme in die zweite Schließweeinrichtung geführt wird,  
 die zweite Schließweeinrichtung so gestaltete abrupte Kanten besitzt, dass bei Gebrauch eine Drehbewegung der Klemme darin verhindert ist,  
 alle Schließweeinrichtungen einen Querschlag am rückseitigen Ende der Hülle (70) besitzen, wobei  
 die Klemmen (64) Schließweggleitflächen bilden, angeordnet zur Erleichterung einer Einführung des Kolbenkörpers (62) in die erste Schließweeinrichtung, wobei die Klemmenschlitz (66) mit dem ersten Schließweeinrichtungsanschlag eingreifen, und zur Erleichterung einer Drehung des Kolbenkörpers (62) in dieser Stellung, so dass die Klemmen (64) in die zweite Schließweeinrichtung geführt werden, unbehindert vom zweiten Schließweganschlag in der Einführrichtung des Kolbenkörpers in die Hülle (70), und zur Erleichterung des Rückzugs des Kolbenkörpers (62) mit den Klemmen (64) in die zweite Schließweeinrichtung an eine Position, wo die Klemmenschlitz (66) mit dem Anschlag an der zweiten Schließweeinrichtung eingreifen, so dass der Kolbenkörper (62) gegen ein Einführen und ein Rückziehen gesichert ist.

10

15

20

25

30

35

40

13. Spritze nach irgendeinem der vorhergehenden Ansprüche, wobei der Kolbenkopf (3) einstückig mit dem Kolbenkörper (2) ist.

45

14. Spritze nach irgendeinem der Ansprüche 1 bis 12, wobei der Kolbenkopf (3) vom Kolbenkörper (2) getrennt ist und mit dem Kolbenkörper (2) unter Ausbildung der Kolbens verbunden werden kann.

50

15. Spritze nach irgendeinem der vorhergehenden Ansprüche, wobei die Schutzhülle (4) und der Kolbenkörper (2) im verpackten Zustand vor einer Verwendung funktionell zueinander angeordnet werden können, wobei das Ende des länglichen Kolbenkörpers (2) entfernt vom Kolbenkopf in Eingriff ist mit den Kolbeneingriffsstrukturen (41, 45), der Flüssigkeitsweg gebildet wird von einer hypodermischen

55

Nadel (14), die längs durch den Kolbenkörper (2) verläuft, wobei deren stirnseitiges Ende (15) aus dem Kolbenkörper (2) vorsteht und aufgenommen ist in und geschützt wird von der Hülle (4) und deren rückseitiges Ende (15) aufgenommen ist in und geschützt wird von dem Kolbenkörper (2).

## Revendications

### 1. Seringue comprenant :

une gaine protectrice généralement tubulaire (4 ; 70) portant des formations d'engagement de piston (41, 45 ; 74) et ayant une extrémité d'aiguille (39) et une extrémité arrière opposée (38 ; 71) ;

un piston (2, 3 ; 60) incluant un corps de piston allongé (2 ; 62) et une tête de piston (3 ; 61), un chemin de fluide (14 ; 65) traversant la tête (3 ; 61) et le corps (2 ; 62) longitudinalement, le corps de piston (2 ; 62) étant positionnable de façon fonctionnelle pour s'étendre à l'intérieur de la gaine (4 ; 70) et être engagé par les formations d'engagement de piston (41, 45 ; 74), avec la tête de piston (3 ; 61) à l'extérieur de la gaine (4 ; 70) et connectée à et en communication de fluide avec le corps de piston (2 ; 62) ;

un élément cylindrique (1 ; 51) qui peut coulisser en une course de décharge en utilisation sur l'extérieur de la tête de piston positionnée de façon fonctionnelle (3 ; 61) et le long de la gaine (4 ; 70) jusqu'à une position déchargée, pour libérer de ce fait les formations d'engagement de piston (41, 45 ; 74), et retenir le piston libéré (2, 3 ; 60), l'élément cylindrique (1 ; 51) pouvant coulisser en opposition depuis la position déchargée pour retirer le piston libéré (2, 3 ; 60) substantiellement de la gaine (4 ; 70) jusqu'à une position verrouillée sûre par rapport à la gaine (4 ; 70) ; caractérisé en ce que l'élément cylindrique (1 ; 51) a une forme et des dimensions qui font qu'il peut coulisser sur l'extérieur de la gaine protectrice (4 ; 70) et lesdites formations d'engagement de piston (41, 45 ; 74) comprennent des pinces (33, 34 et 20, 21 ; 64) et des arrêts (41, 45 ; 74) portés par le corps de piston (2 ; 62) et la gaine (4 ; 70) pour bloquer de façon fonctionnelle le corps de piston (2 ; 62) par rapport à la gaine (4 ; 70) pour conserver une aiguille utilisée avec la seringue à l'intérieur de la gaine (4 ; 70) avant et après utilisation.

2. Seringue selon la revendication 1, dans laquelle le corps de piston (2) a une extrémité avant et une extrémité arrière, et des pinces avant (33, 34) et des

- pincés arrière (20, 21) dessus, et la gaine (4) a des arrêts (41, 45) en son extrémité arrière (38), les pincés (20, 21, 33, 34) et les arrêts (41, 45) étant agencés de façon à permettre au corps de piston (2) d'être inséré dans la gaine (4) avec les pincés arrière (20, 21) du corps de piston (2) coopérant avec les arrêts (41, 45) de la gaine et bloquant le corps de piston (2) contre le retrait de la gaine (4) et l'insertion dans celle-ci, dans cette orientation rotative avec la gaine (4), et étant en outre agencés de façon à permettre le mouvement de l'élément cylindrique (1) jusqu'à sa position déchargée pour libérer les pincés arrière (20, 21) du corps de piston et pour permettre aux pincés avant (33, 34) du corps de piston de coopérer avec les arrêts (41, 45) lors du mouvement du corps de piston (2) jusqu'à la position verrouillée sûre.
3. Seringue selon la revendication 2, dans laquelle la gaine (4) a des premier et deuxième moyen de trou de serrure axial (44, 40), le premier moyen de trou de serrure (44) ayant une section dont la forme est conçue pour guider une pince tournant dedans en utilisation dans le deuxième moyen de trou de serrure (40), et le deuxième moyen de trou de serrure (40) ayant des bords abrupts conçus pour empêcher le mouvement rotatif d'une pince dedans en utilisation.
  4. Seringue selon la revendication 3, dans laquelle les premier et deuxième moyens de trou de serrure sont formés par des paires respectives de trous de serrure conjugués diamétralement opposés (44, 40), les paires étant situées à 90 degrés l'une par rapport à l'autre dans l'orientation de coupe transversale de la gaine (4).
  5. Seringue selon la revendication 4, dans laquelle l'un desdits arrêts (41, 45) est un arrêt à pince transversale (45) prévu dans chaque trou de serrure d'une paire, l'arrêt à pince (45) de la première paire de trous de serrure étant situé plus à l'intérieur de la gaine que l'arrêt à pince (41) de la deuxième paire de trou de serrure.
  6. Seringue selon la revendication 5, dans laquelle les pincés avant (33, 34) du corps de piston (2) forment des coulisseaux de trou de serrure, et ont des formations de pincement opposées, comprenant une formation avant qui est apte à coulisser sur les arrêts uniquement dans une direction avant, et une formation arrière qui est apte à coulisser sur les arrêts uniquement dans une direction de retrait.
  7. Seringue selon la revendication 6, dans laquelle les pincés arrière (20, 21) du corps de piston (2) ont des formations de pincement opposées, comprenant une formation de pincement avant apte à coulisser sur les arrêts (45) lors de l'insertion dans la gaine, et une formation arrière qui bute contre les arrêts quand on fait coulisser le corps de piston (2) dans la gaine (4).
  8. Seringue selon la revendication 7, dans laquelle la formation arrière des pincés arrière (20, 21) du corps de piston est formée de façon à coopérer avec la tête de piston (3), lors du mouvement de la tête de piston (3) avec l'élément cylindrique (1) à l'extrémité de la course de décharge en utilisation, pour dégager la formation avant de la pince arrière de son arrêt en utilisation.
  9. Seringue selon la revendication 1, dans laquelle les arrêts (74) sur la gaine (70) comprennent des volets barbelés agencés de façon à coopérer avec des fentes (66) réalisées sur le piston (60).
  10. Seringue selon la revendication 9, dans laquelle les volets font partie de la paroi de la gaine et font saillie axialement vers l'arrière depuis une partie articulée de la gaine (70) à l'extrémité d'aiguille de la gaine (70), la gaine (70) ayant des extrémités libres (75) aptes à coopérer avec l'extrémité (54) de l'élément cylindrique (51) à l'extrémité d'une course de décharge pour articuler les volets vers l'extérieur et les dégager des fentes (66).
  11. Seringue selon la revendication 10, dans laquelle les fentes (66) sont portées dans des pincés de piston (64) diamétralement opposées qui s'étendent axialement depuis le corps de piston (62) à une extrémité avant de celui-ci, et sont déformables vers l'intérieur de façon résiliente.
  12. Seringue selon la revendication 11, dans laquelle la gaine (70) a des premier et deuxième moyen de trou de serrure axial, le premier moyen de trou de serrure ayant une section dont la forme est conçue pour guider une pince tournant dedans dans le deuxième moyen de trou de serrure, et le deuxième moyen de trou de serrure ayant des bords abrupts conçus pour empêcher le mouvement rotatif d'une pince dedans en utilisation, chaque moyen de trou de serrure ayant un arrêt transversale à l'extrémité arrière de la gaine (70), et dans laquelle les pincés (64) forment des coulisseaux de trou de serrure, agencés de façon à permettre l'insertion du corps de piston (62) dans le premier moyen de trou de serrure avec les fentes à pince (66) engagées dans le premier arrêt de moyen de trou de serrure, et pour permettre la rotation du corps de piston (62) à cet emplacement pour guider les pincés (64) dans le deuxième moyen de trou de serrure, libre de l'arrêt du deuxième moyen de trou de serrure dans une direction d'insertion du corps de piston dans la gaine (70), et pour permettre en outre le retrait du corps

de piston (62) avec les pinces (64) dans le deuxième moyen de trou de serrure jusqu'à une position où les fentes à pince (66) coopèrent avec l'arrêt au deuxième moyen de trou de serrure pour bloquer le corps de piston (62) contre l'insertion et le retrait. 5

13. Seringue selon l'une quelconque des revendications précédentes, dans laquelle la tête de piston (3) est intégrée au corps de piston (2). 10

14. Seringue selon l'une quelconque des revendications 1 à 12, dans laquelle la tête de piston (3) est distincte du corps de piston (2) et peut être connectée au corps de piston (2) pour former le piston. 15

15. Seringue selon l'une quelconque des revendications précédentes, la gaine protectrice (4) et le corps de piston (2) pouvant être positionnés de façon fonctionnelle l'un par rapport à l'autre avant utilisation dans un état emballé dans lequel l'extrémité du corps de piston allongé (2) éloignée de l'extrémité de tête de piston est engagée dans la formation d'engagement de piston (41, 45), le chemin de fluide étant formé par une aiguille hypodermique (14) allant dans le sens de la longueur à travers le corps de piston (2) avec son extrémité avant (1) s'étendant à l'extérieur du corps de piston (2) et contenue à l'intérieur de et protégée par la gaine (4), et avec son extrémité arrière (15) contenue à l'intérieur de et protégée par le corps de piston (2). 20  
25  
30

35

40

45

50

55

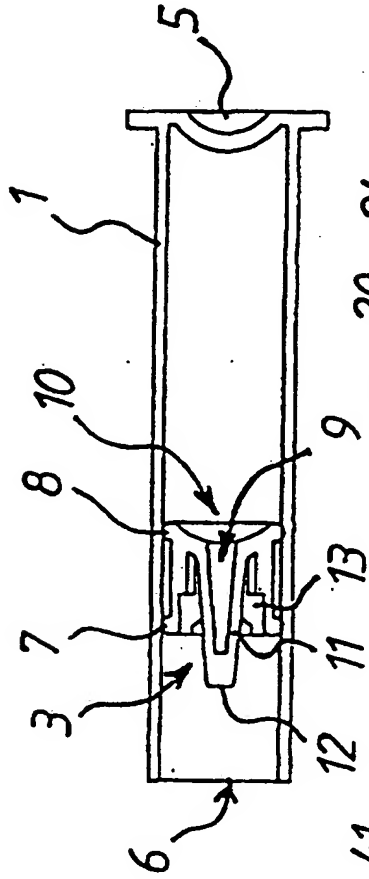


FIG 1.

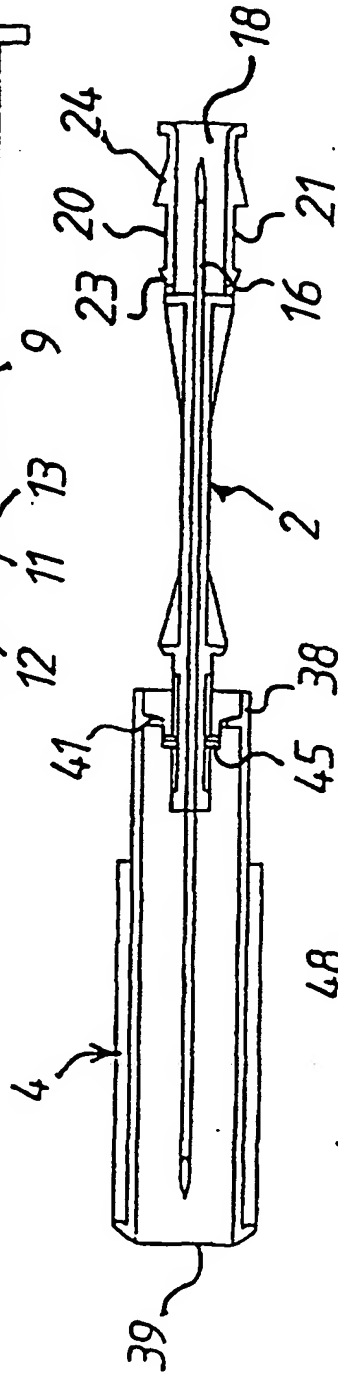


FIG 2.

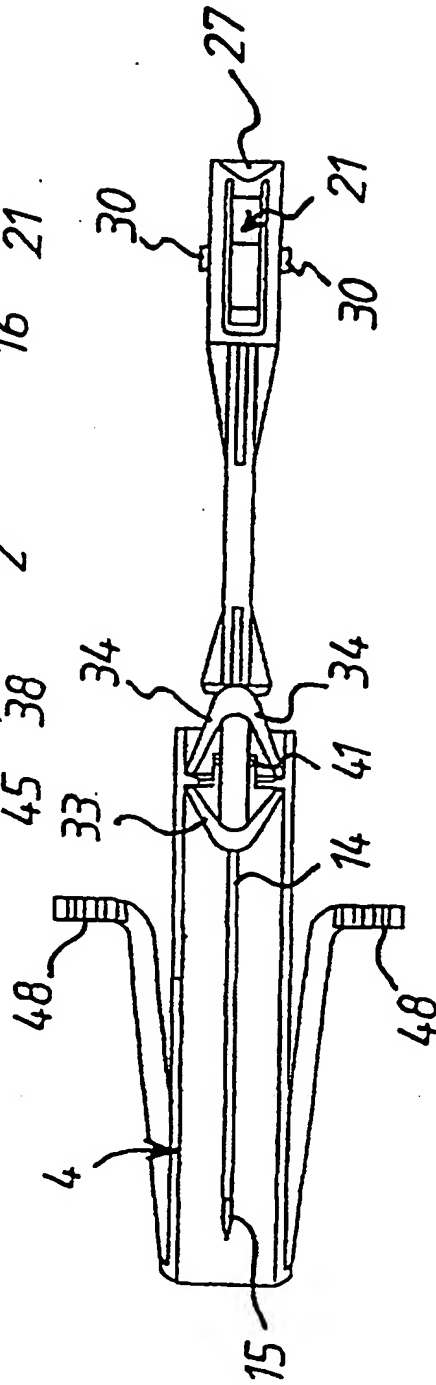
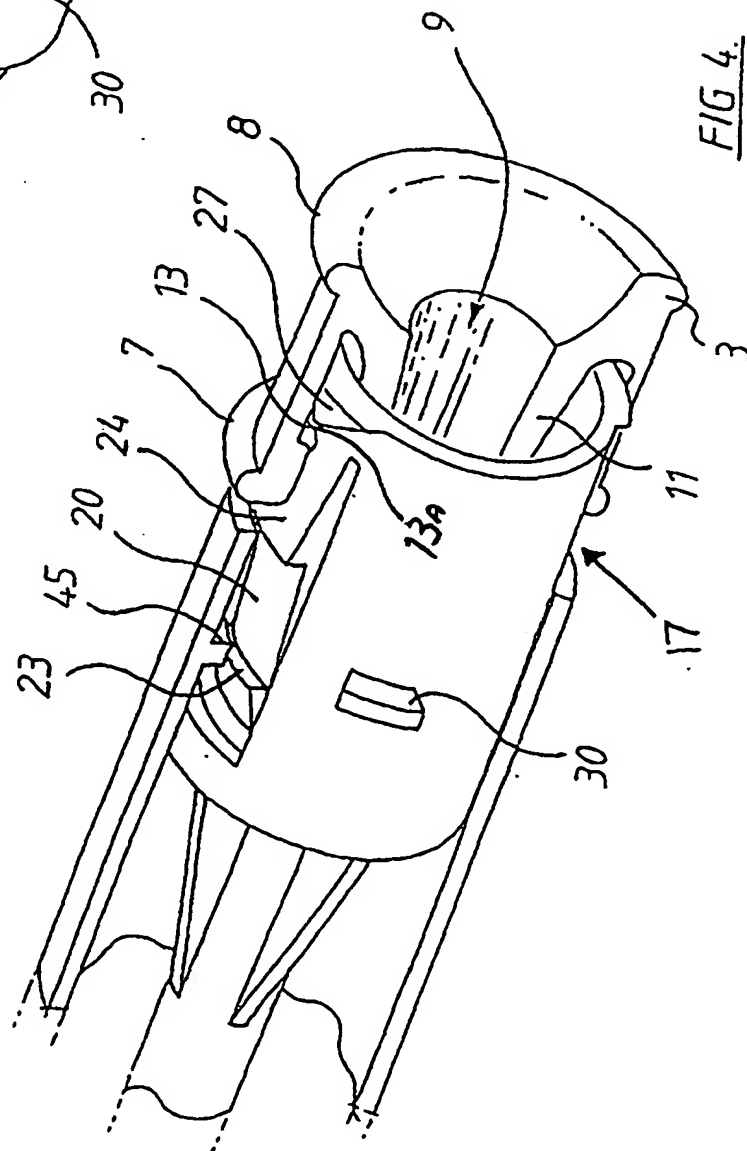
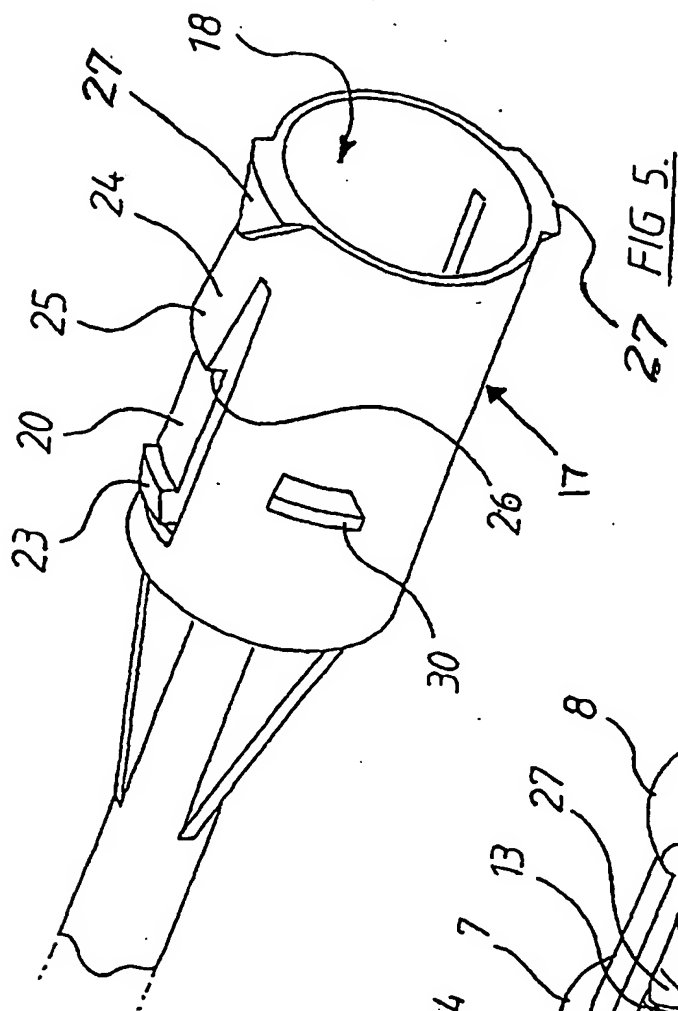


FIG 3.



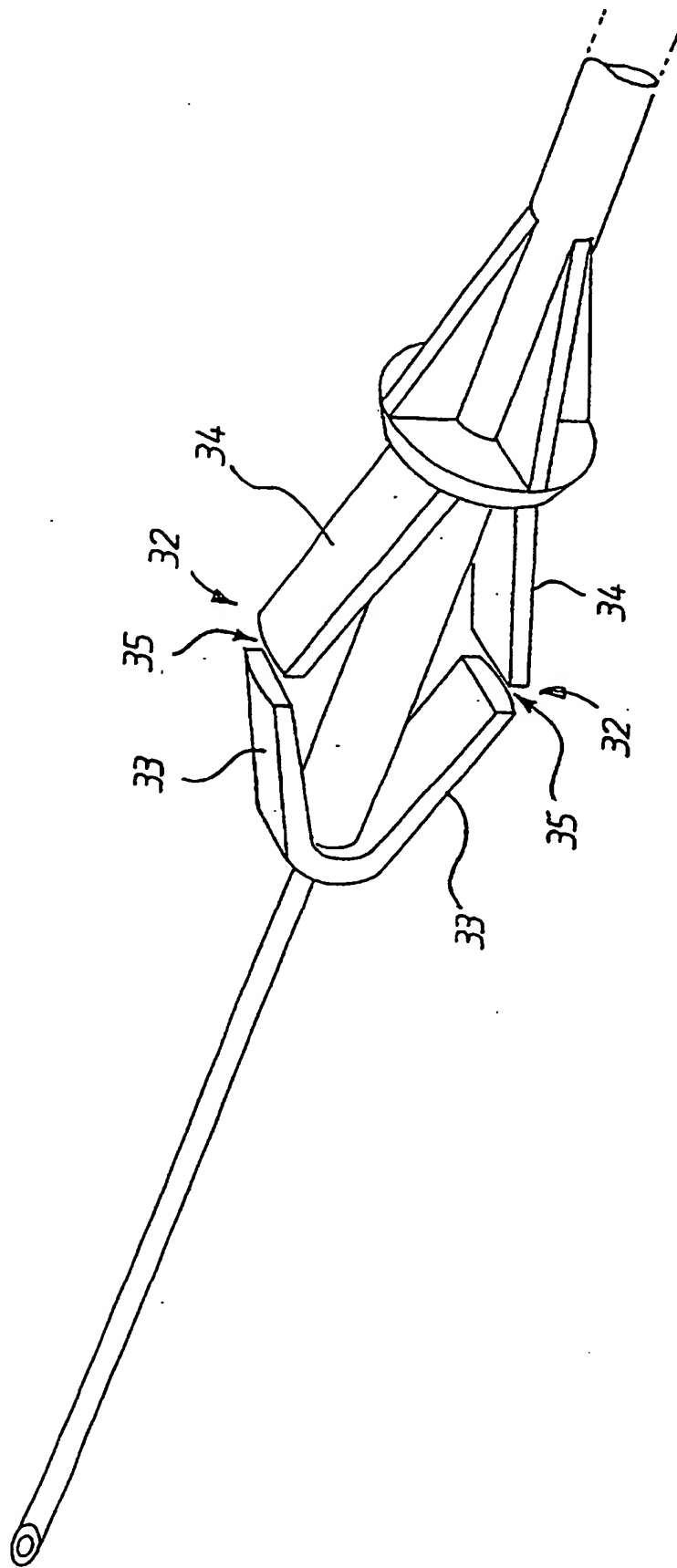


FIG 6.

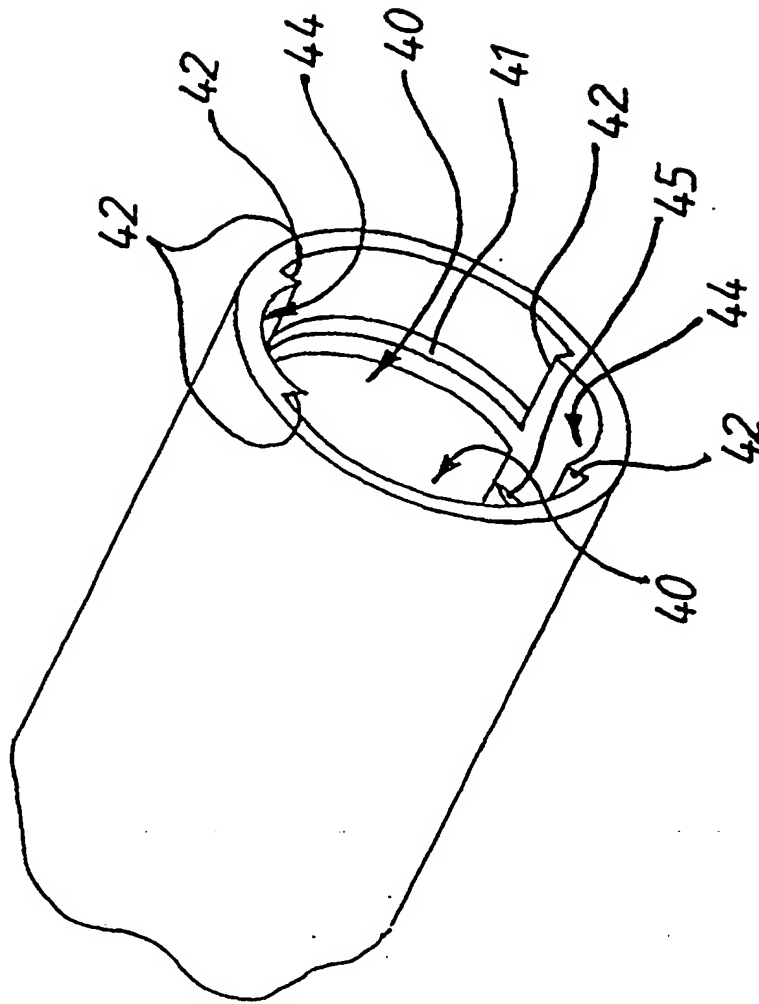


FIG 7.



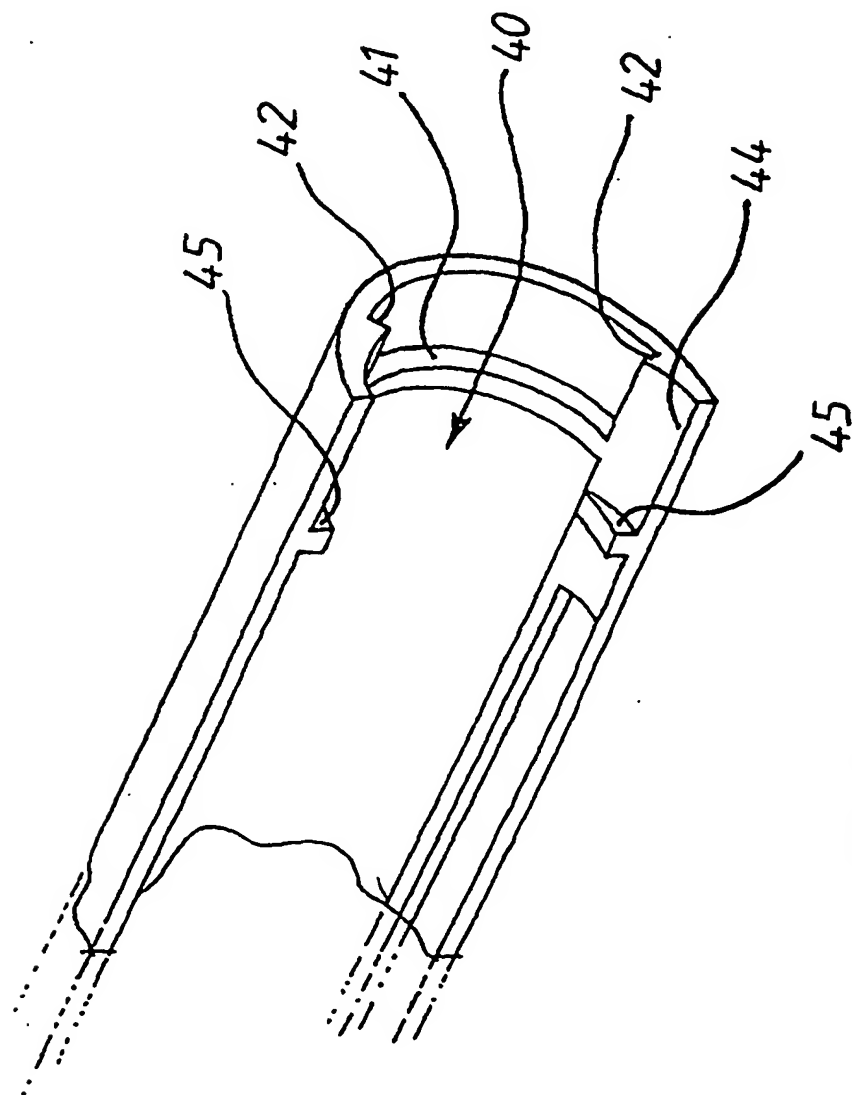
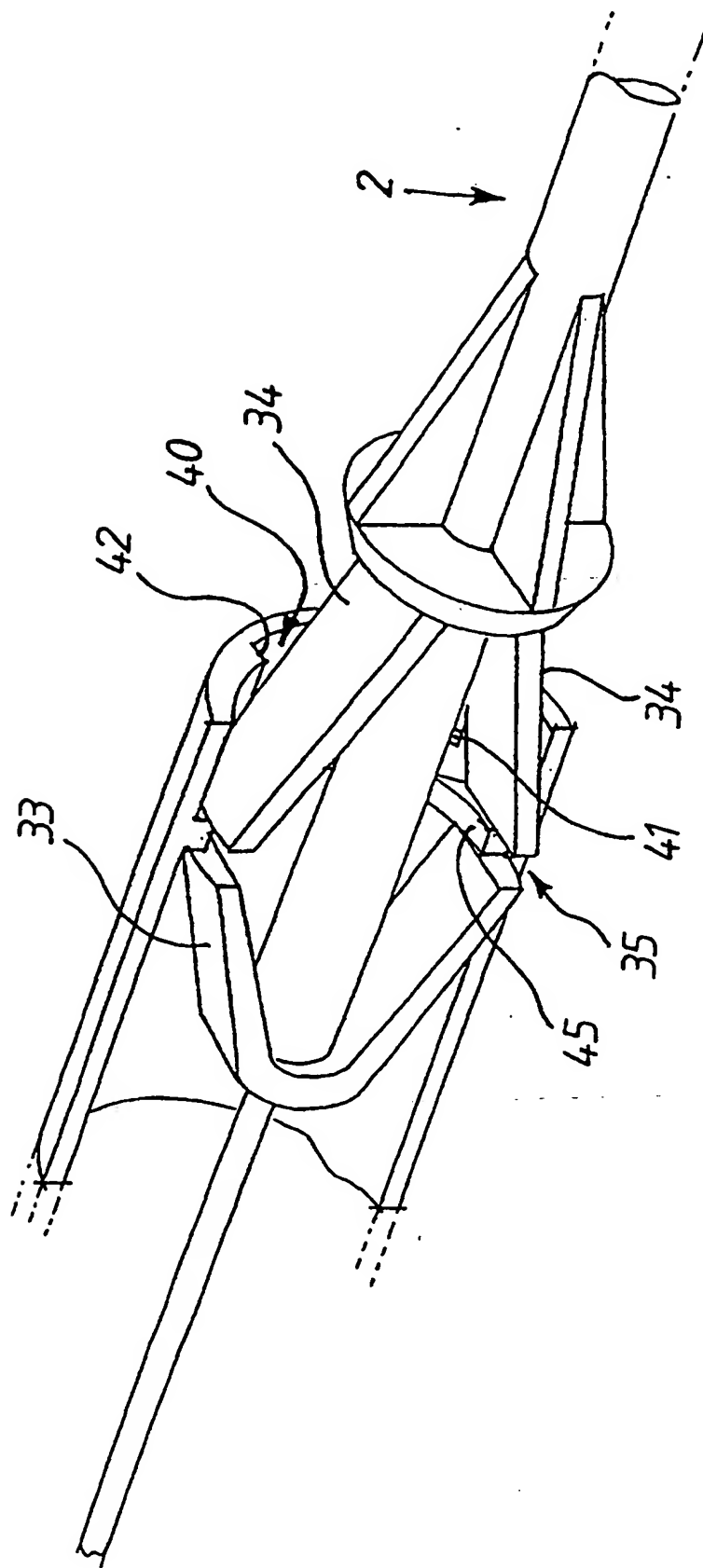


FIG 8.



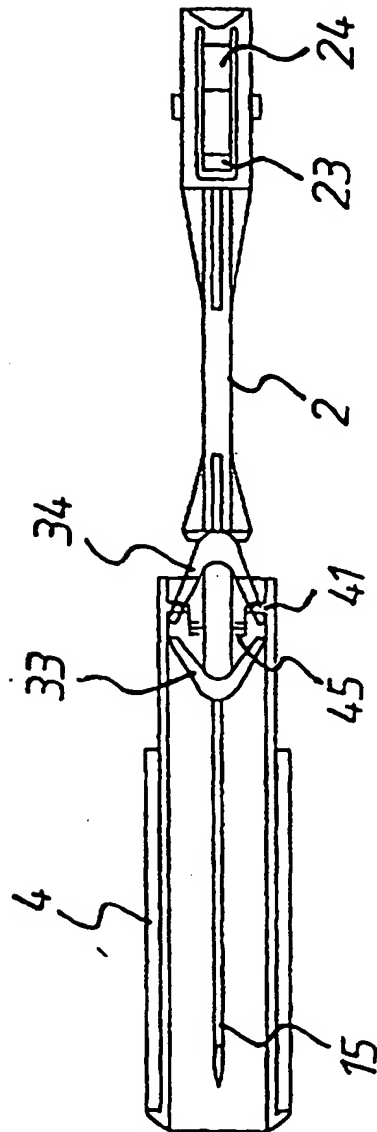


FIG 10.

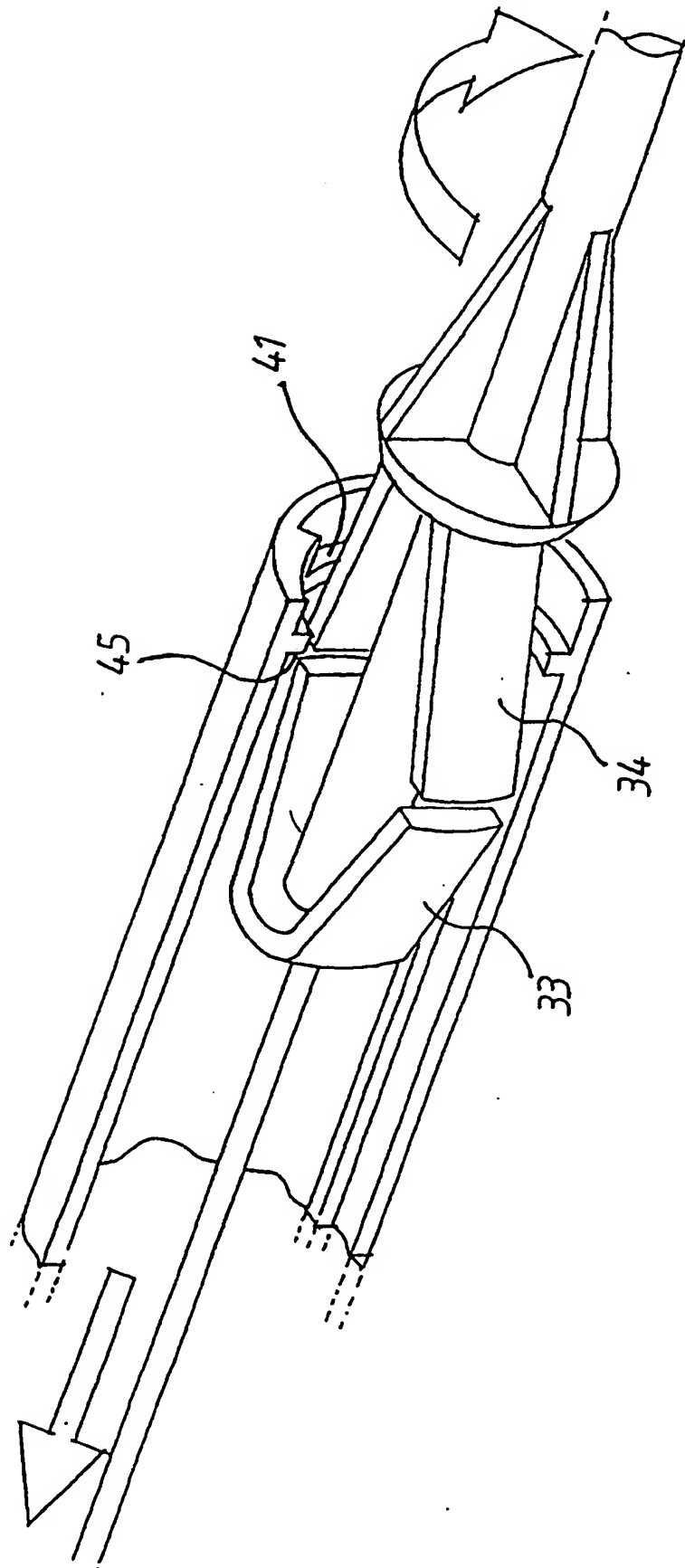


FIG 11.

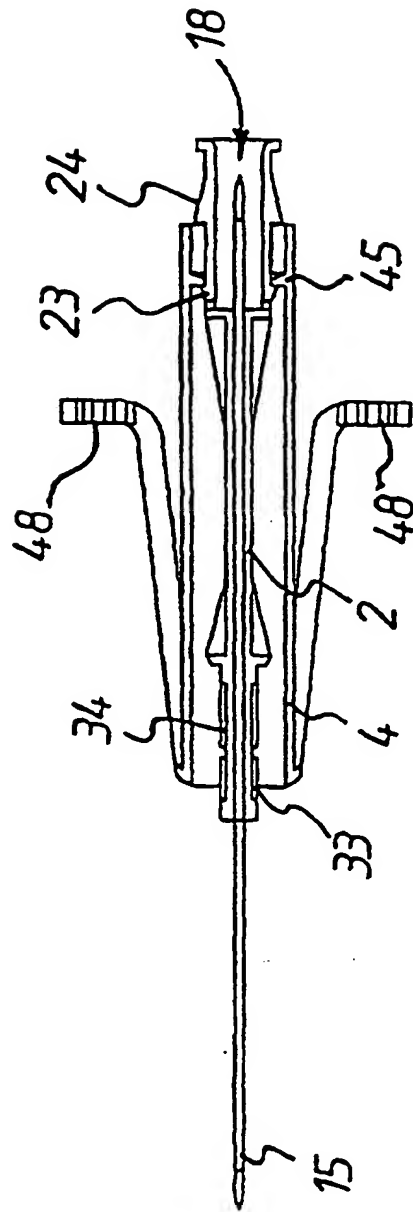


FIG 12.

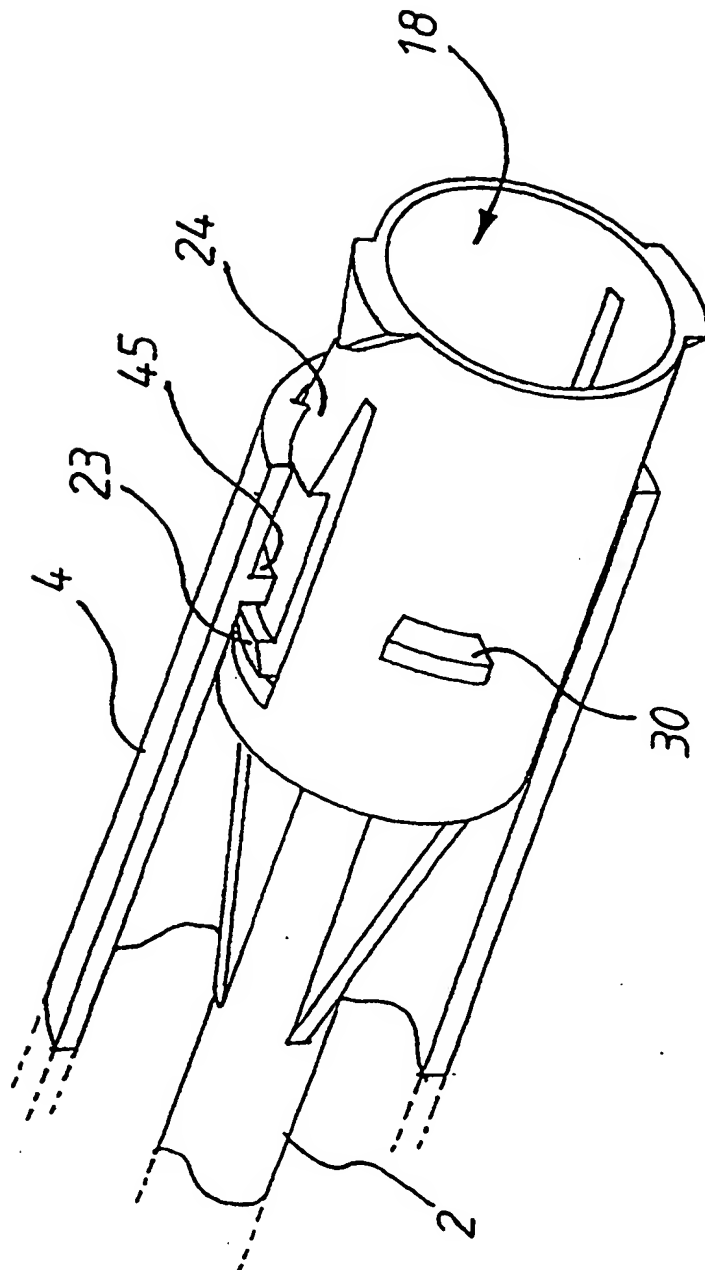
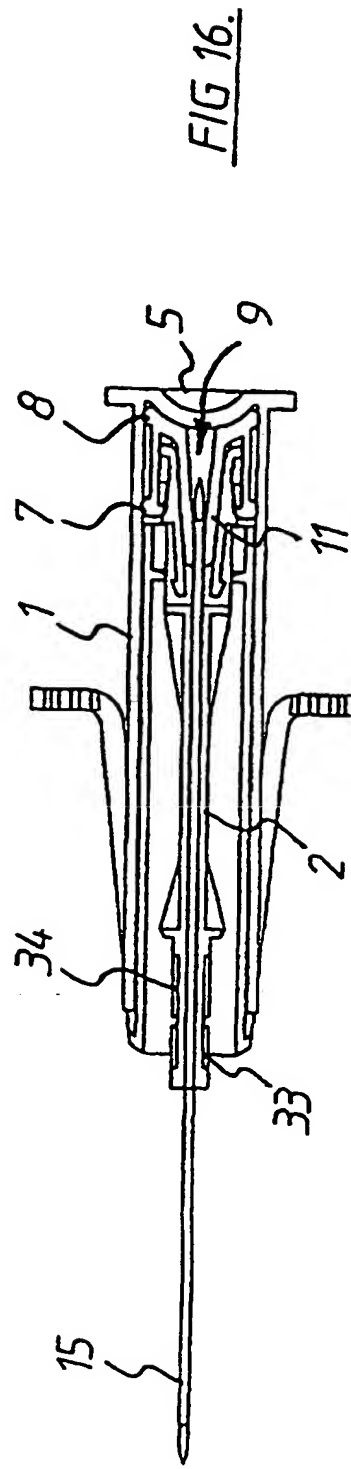
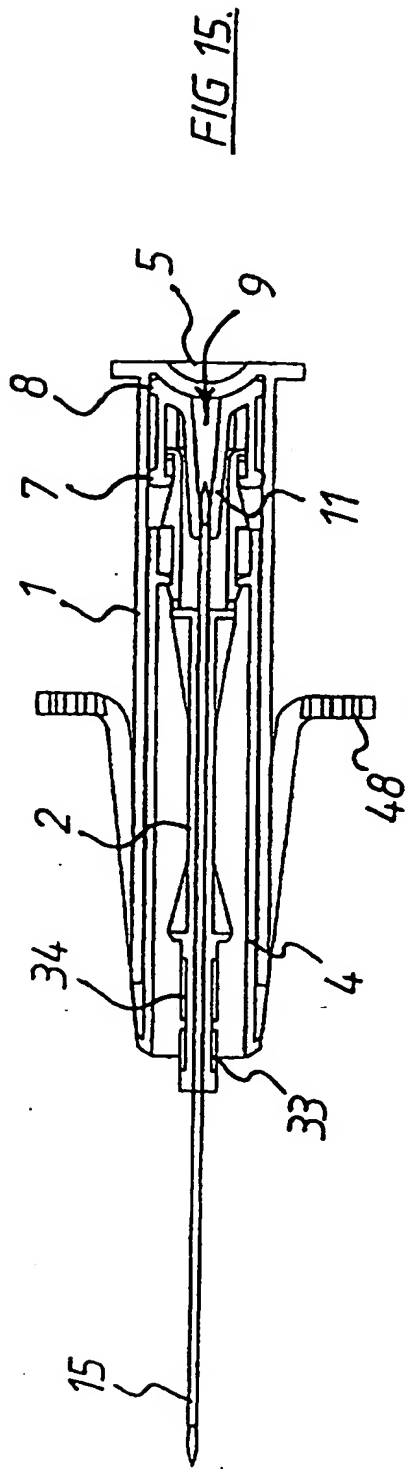
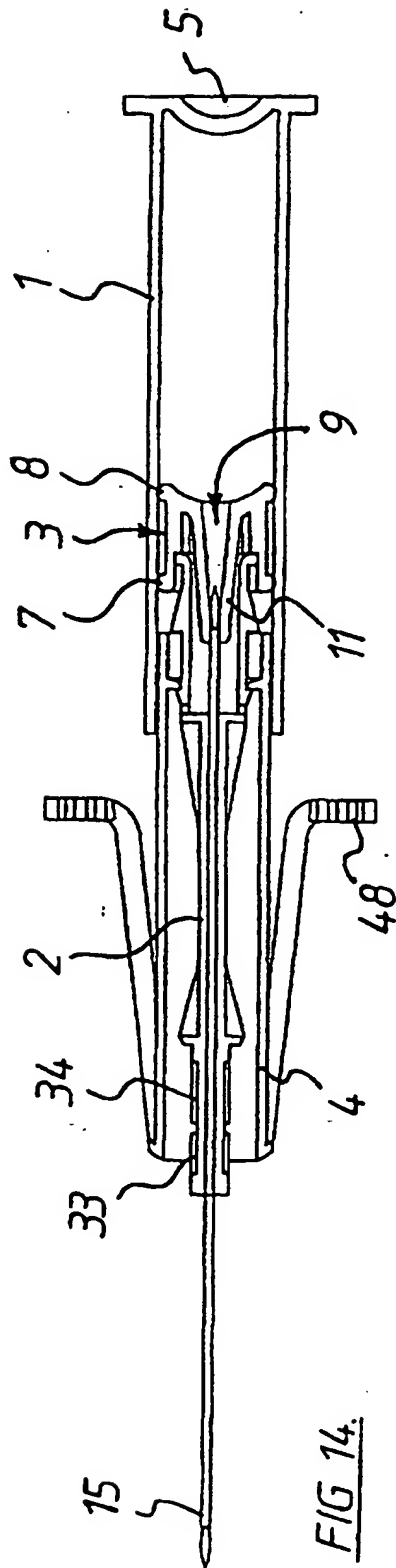


FIG 13.



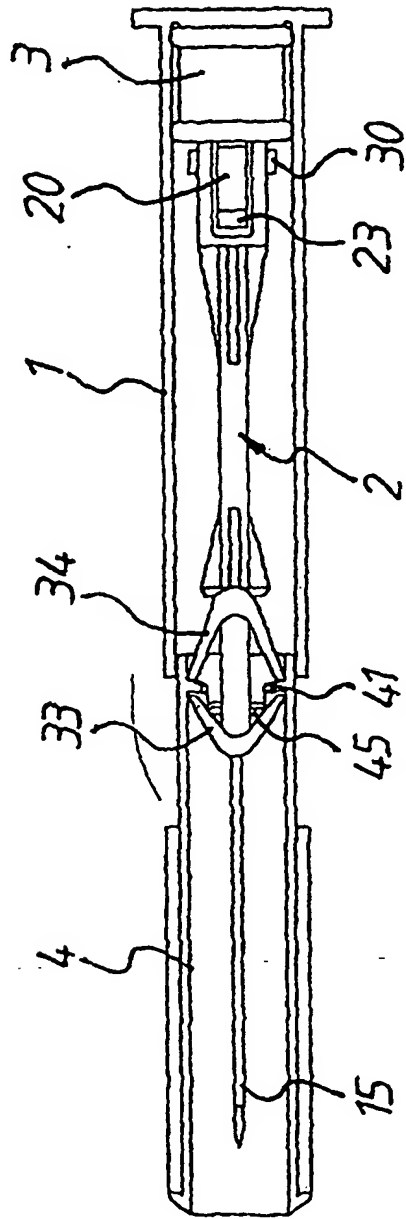


FIG 17.



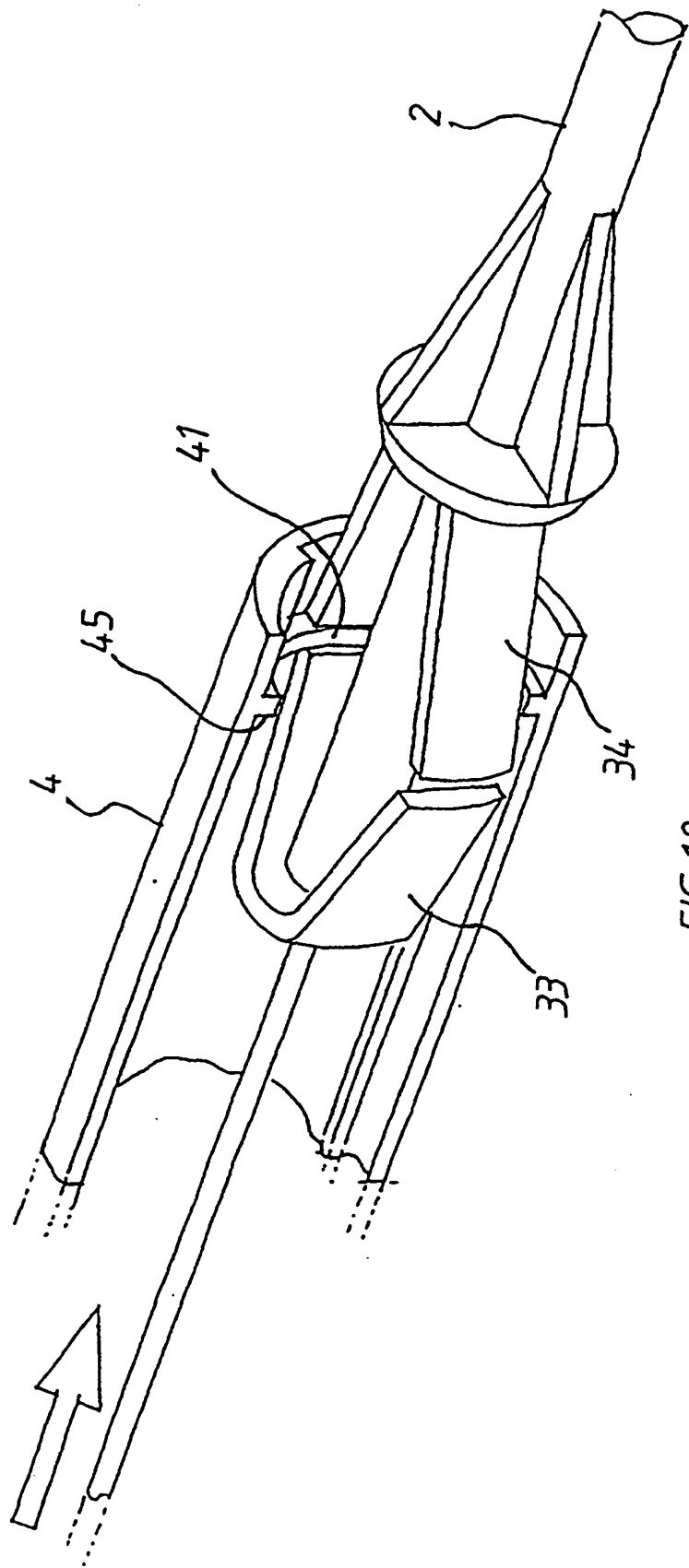
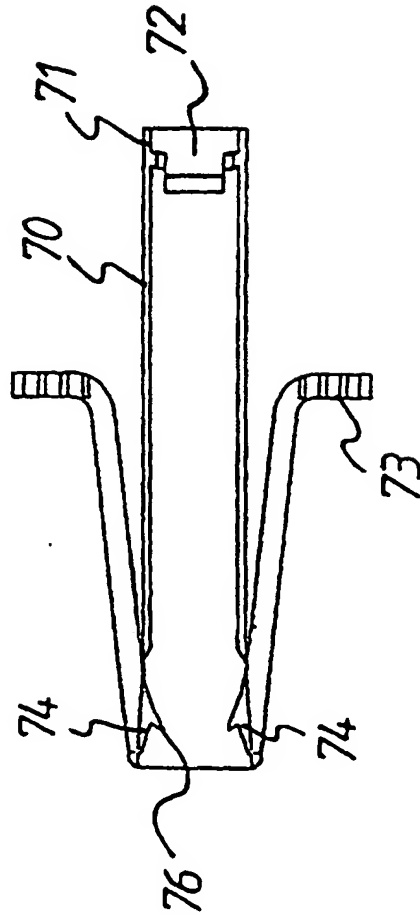
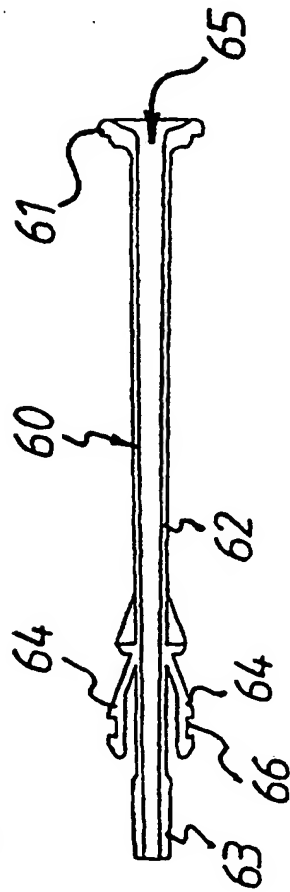
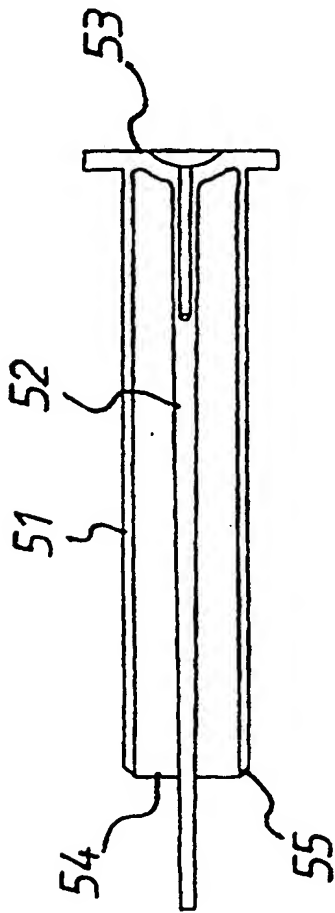


FIG 18



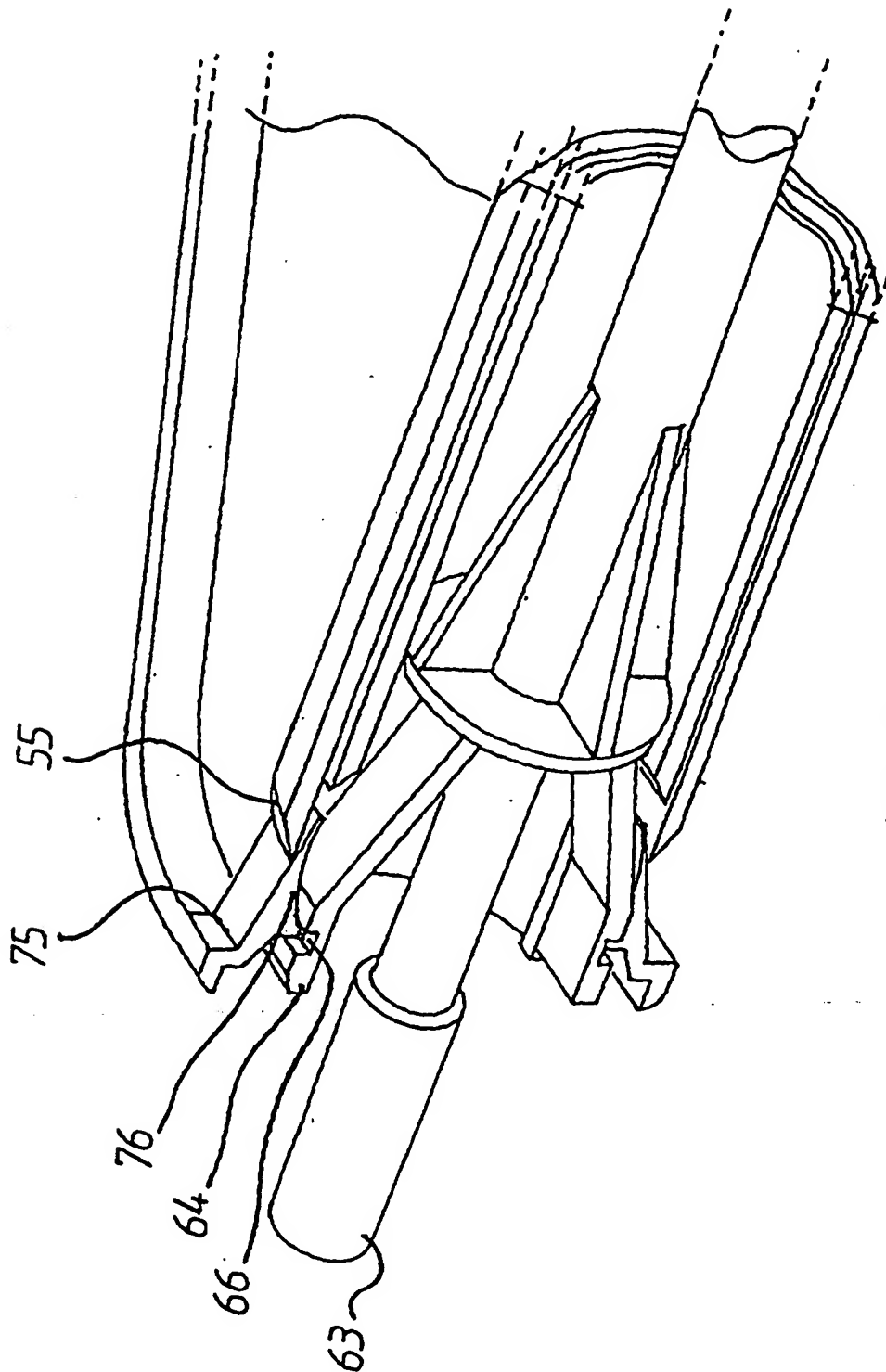


FIG 22.

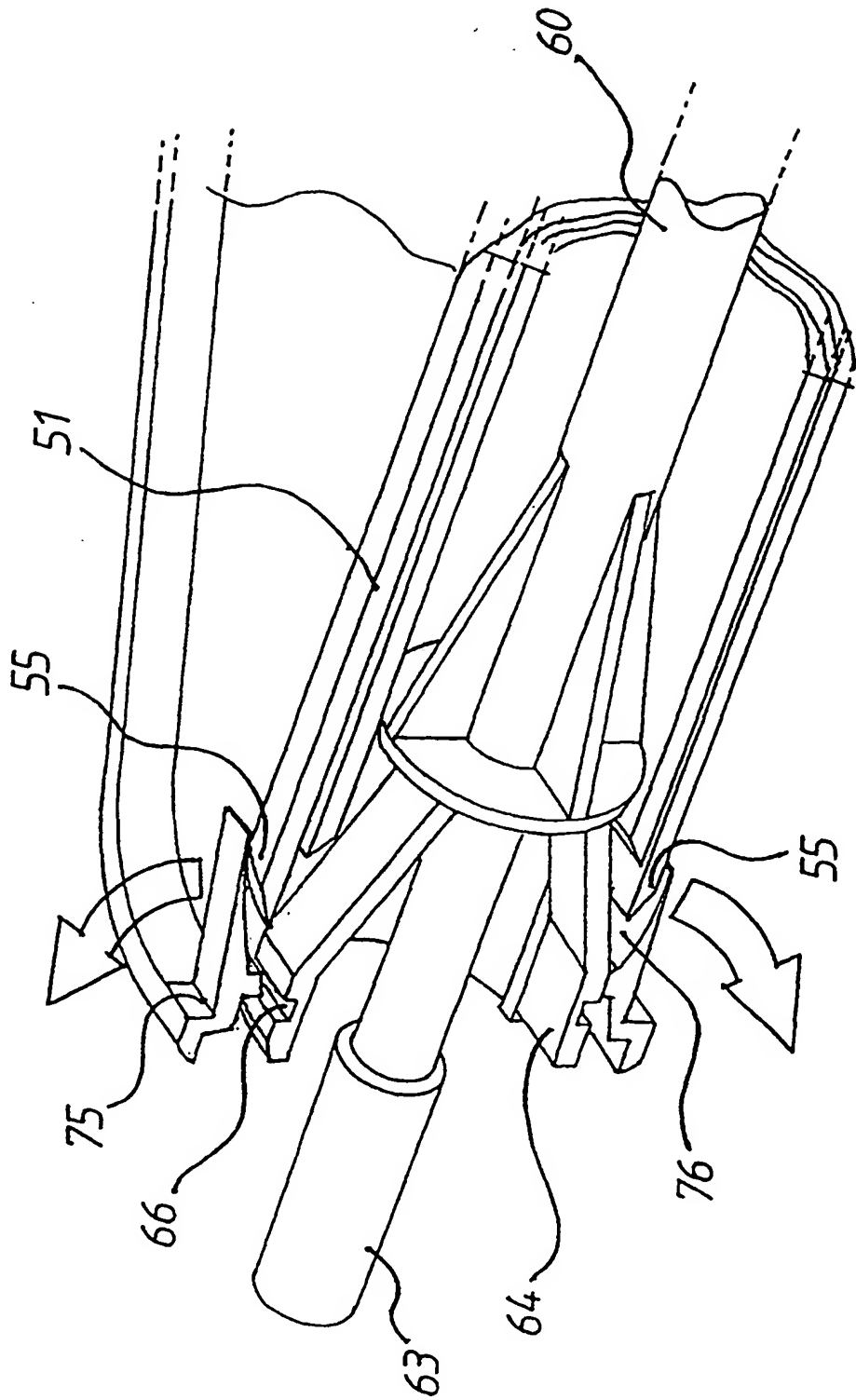


FIG 23.